# General

## Guideline Title

Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block (part review of technology appraisal guidance 88).

## Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block (part review of technology appraisal guidance 88). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Nov. 55 p. (Technology appraisal guidance; no. 324).

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Institute for Clinical Excellence (NICE). Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block. London (UK): National Institute for Clinical Excellence (NICE); 2005 Feb. 36 p. (Technology appraisal; no. 88).

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Recommendations

## Major Recommendations

Dual-chamber pacemakers are recommended as an option for treating symptomatic bradycardia due to sick sinus syndrome without atrioventricular block.

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

Symptomatic bradycardia due to sick sinus syndrome without atrioventricular block

## Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

## Clinical Specialty

Cardiology

Internal Medicine

## Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To evaluate the clinical effectiveness and cost-effectiveness of dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block

## Target Population

Patients with symptomatic bradycardia due to sick sinus syndrome without atrioventricular block

## Interventions and Practices Considered

Dual-chamber pacemakers

## Major Outcomes Considered

- Clinical effectiveness
  - All-cause mortality
  - Incidence of stroke
  - Incidence of atrial fibrillation
  - Incidence of heart failure
  - Exercise capacity
  - Need for further surgery
  - Symptoms of fatigue, dyspnoea, chest pain, dizziness, palpitations and sleep disturbance
  - Cognitive function
  - Health-related quality of life
  - General well-being
  - Adverse events of implantation (peri- and post-operative complications, atrial fibrillation and device replacement)
- Cost-effectiveness

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

## Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the BMJ Technology Assessment Group (BMJ-TAG) (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Identification of Studies

To identify relevant randomised controlled trials (RCTs), multiple electronic databases were searched, including MEDLINE, EMBASE, and The Cochrane Library (including the Cochrane Database of Systematic Reviews [CDSR], Cochrane Central Register of Controlled Trials [CENTRAL], Database of Abstracts of Reviews of Effects [DARE], and Health Technology Assessment Database [HTA database]). Bibliographies of retrieved studies identified as relevant were manually reviewed for potentially eligible studies. In addition, experts in the field were contacted with a request for details of published and unpublished studies of which they may have knowledge. Furthermore, submissions submitted to NICE were assessed for unpublished data.

The search terms included Medical Subject Headings (MeSH) and text terms for the interventions: artificial pacemakers and pacing; dual-chamber pacemakers/pacing; and single-chamber atrial pacemakers/pacing. As the scoping search using this search strategy identified all relevant trials known from the previous Multiple Technology Appraisal (MTA), search terms for the condition (i.e., bradycardia and sick sinus syndrome [SSS]) were not used. To keep in line with the original MTA, which focused on RCT evidence, the search strategy included an RCT filter developed and validated by Scottish Intercollegiate Guidelines Network. No language or date restriction was applied to the searches. Electronic databases were initially searched on 7 January 2014 and results uploaded into Reference Manager Version 11.0 and deduplicated. An update search was carried out 12 May 2014. Full details of the terms used in the searches are presented in Appendix 1 in the assessment report.

Two reviewers independently screened all titles and abstracts according to the inclusion criteria. Full paper manuscripts of any titles/abstracts of potential relevance were obtained and assessed independently by two reviewers. If a study was only reported as a meeting abstract or if full paper manuscripts could not be obtained, the study authors were contacted to gain further details. Studies for which insufficient methodological details were available to allow critical appraisal of study quality were excluded. Discrepancies between the two reviewers were resolved by consensus, with involvement of a third reviewer when necessary.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria for the review of effectiveness were based on the decision problem outlined in the table below. The review included RCTs of parallel and crossover design. Systematic reviews and non-randomised studies were excluded.

The intervention was permanent implantable dual-chamber pacemakers compared with single-chamber atrial pacemakers or dual-chamber pacemakers programmed primarily to atrial pacing. Studies were not excluded based on programming of the pacemakers; both rate and non-rate responsive programming were included. The review also allowed other programmable features, such as prolonging or eliminating the atrioventricular (AV) interval in order to minimize ventricular pacing.

RCTs were included if the relevant pacing modes were compared in a population with symptomatic bradycardia, documented SSS, bradycardia-tachycardia syndrome, and normal AV conduction. Studies were excluded if none of the outcomes of interest was reported.

Table. Inclusion Criteria, Based on the Decision Problem, for Studies Evaluating Clinical Effectiveness

| | Inclusion Criteria |
|---|---|
| Study Design | Randomized controlled trials of parallel or crossover design |
| Intervention | Permanent implantable dual-chamber pacemakers |
| Population | People with symptomatic bradyarrythmias due to sick sinus syndrome without atrioventricular block |
| Comparator | Permanent implantable single-chamber atrial pacemakers |
| Outcomes | • Mortality (all-cause)<br>• Heart failure<br>• Atrial fibrillation<br>• Stroke<br>• Exercise capacity<br>• Cognitive function<br>• Requirement for further surgery<br>• Adverse effects of pacemaker implantation (including peri- and post-operative complications, atrial fibrillation and device replacement)<br>• Health-related quality of life (HRQoL) |

Assessment of Cost-effectiveness

Systematic Review of Existing Cost-effectiveness Evidence

A systematic review of MEDLINE (Ovid), EMBASE (Ovid), HTA database (HTA, Cochrane Library) and National Health Service Economic Evaluation Database (NHS EED) (Cochrane Library) was carried out in December 2013. The review aimed to identify published economic evaluations or costing studies of relevance to the decision problem that is the focus of this MTA.

To facilitate the identification of all potentially relevant information, the MEDLINE and EMBASE search strategies combined terms capturing population (pacing), interventions (dual-chamber pacemakers) and economic evaluations/costing studies with terms designed to capture a broader range of comparators (e.g., single-chamber ventricular pacemakers) than those specified in the scope: economic evaluations or costing studies in patients receiving single-chamber ventricular pacing were considered likely to be informative in the development of a *de novo* economic evaluation.

The search strategy for HTA and NHS EED combined terms for the target condition (AV block, SSS) with terms for the intervention (pacemaker). All databases were searched from inception: full details of the search terms are presented in Appendix 1 in the assessment report.

In addition to searches of the above databases, additional sources of potentially relevant publications were explored:

- Experts in the field were contacted with a request for details of relevant published and unpublished studies of which they may have knowledge.
- The NICE website was searched for any recently published Technology Appraisals in pacing that had not already been identified via the database searches.
- Reference lists of key identified studies were reviewed for any potentially relevant studies.

No restrictions on language or setting were applied to any of the searches. The titles and abstracts of papers identified through the searches were independently assessed for inclusion by two health economists using the criteria outlined in the table below.

Table. Inclusion and Exclusion Criteria for the Systematic Review of Economic Evaluations and Costing Studies

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| • All full economic evaluations (cost-effectiveness, cost-benefit, cost-consequence or cost minimisation) | • Abstracts with insufficient methodological details |

| Inclusion Criteria | Exclusion Criteria |
| --- | --- |
| • All UK resource use or costing studies<br>• Any setting (to be as inclusive as possible)<br>• Disease area is atrioventricular block and/or sick sinus syndrome<br>• Intervention is pacing | • Systematic reviews |

The systematic review was updated in June 2014. The search strategy remained the same as outlined above; however, results were limited from 16 December 2013 to 6 June 2014 to identify additional relevant studies.

## Number of Source Documents

Assessment of Clinical Effectiveness

Database searches retrieved 492 records (post deduplication). One additional reference was identified through hand searching, giving a total of 493 references that were screened for inclusion (see Figure 1 in the assessment report [see the "Availability of Companion Documents" field] for studies included and excluded from the clinical effectiveness review). Full references were sought for 34 of these references, which were potentially eligible for inclusion. Of the records identified as potentially relevant, only one reference was unobtainable. However, this reference was identified in the original Multiple Technology Appraisal (MTA) TA88 and excluded because it was a pre-clinical study. Of 33 records which were potentially eligible for inclusion, 9 references describing 6 studies were included in the review.

Assessment of Cost-effectiveness

- Eleven papers from the December 2013 search were identified as relevant to the review of the economic literature. A further nine papers were identified from the update search in June 2014. Of these, seven were excluded on the basis of title and abstract, one was a duplicate, and one paper was identified as potentially relevant and reviewed in full. Of the 12 studies identified from the searches, 11 were economic evaluations and one was a UK-specific costing study.
- The Technology Assessment Group (TAG) submitted a *de novo* economic model.

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

## Rating Scheme for the Strength of the Evidence

Not applicable

## Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the BMJ Technology Assessment Group (BMJ-TAG) (see the "Availability of Companion Documents" field).

Assessment of Clinical Effectiveness

Data Abstraction Strategy

Data were extracted independently by two reviewers using a standardised data extraction form. Information extracted included details of the study's design and methodology, baseline characteristics of participants, and results, including clinical outcome efficacy and any adverse events reported. Where there was incomplete information, the study authors were contacted with a request for further details. Discrepancies were resolved by discussion, with involvement of a third reviewer if necessary. Data extraction forms for the included studies are provided in Appendix 2 in the assessment report (see the "Availability of Companion Documents" field).

Critical Appraisal Strategy

The quality of the clinical effectiveness studies were assessed independently by two reviewers. Any disagreements were resolved by consensus and if necessary a third reviewer was consulted. The study quality was assessed according to recommendations by the Centre for Reviews and Dissemination (CRD) and the Cochrane Handbook for Systematic Reviews of Interventions and recorded using the Cochrane Risk of Bias Tool.

Methods of Data Synthesis

Details of results on clinical effectiveness and quality assessment for each included study are presented in structured tables and as a narrative summary. The possible effects of study quality on the effectiveness data and review findings are discussed. Standard pair-wise meta-analysis was performed to evaluate the clinical effectiveness for several outcomes based on intention-to-treat (ITT) analysis. ITT was defined as patients being analysed in the trial arm to which they were allocated at randomisation regardless of whether they changed pacing mode, withdrew or were lost to follow-up.

Dichotomous outcomes data were meta-analysed using Mantel-Haenzsel odds ratio (OR) with 95% confidence interval (CI) and a random effects model. Individual trial data were analysed and presented in the same way as meta-analysed data for comparison where appropriate. In addition, if hazard ratios were presented in the original publication of a trial, these have been reproduced in this report for comparison. Missing data were imputed and analysed as treatment failures.

For the dichotomous outcomes reported in this review (mortality, heart failure, atrial fibrillation, stroke, further surgery, and adverse events), only randomised controlled trials (RCTs) with a parallel group design have been considered, excluding RCTs with a crossover design. RCTs with a crossover design are most appropriate for symptomatic treatment of chronic or relatively stable conditions, such as symptomatic bradycardia treated by artificial pacing with a permanently implanted pacemaker. However, crossover trials are only appropriate when looking at treatment effects that are likely to be reversible and short-lived, and inappropriate when studying outcomes where an outcome event may alter the baseline risk, that is, on entry to the second phase the patients systematically differ from their initial state.

Data for the continuous outcomes exercise capacity, cognitive functioning, and quality of life were primarily reported in included crossover trials. Data from parallel and crossover RCTs have been reported separately. It was planned *a priori* to analyse continuous outcome data from crossover studies using the mean difference (or the difference between the means) of dual-chamber and single-chamber atrial pacing, and the standard deviation (SD) or standard error (SE) for the within-person differences. However, the included crossover trials reported means and SD for treatment-specific outcomes, but did not report paired results. One crossover trial provided individual patient data (IPD) for exercise capacity and one for quality of life from which the mean difference and SE for within-person difference could be obtained. However, because of the lack in reporting of relevant data across the included crossover trials, meta-analysis of data was not performed.

Meta-analysis was carried out using Review Manager, with the use of a random-effects model. Statistical heterogeneity between included studies was assessed using the $I^2$ test. In the presence of heterogeneity ($I^2$>30%), possible sources were investigated, including differences between individual studies' populations, methods or interventions. The possibility of publication bias and/or small study effects was not investigated because of the low number of included studies.

Assessment of Cost-effectiveness

Model Structure

The Technology Assessment Group (TAG) economic model is a Markov cohort model consistent with that used in TA88, of which this Multiple Technology Appraisal (MTA) is, in part, an update. Furthermore, to facilitate a comparison of the cost-effectiveness of dual-chamber pacemakers versus single-chamber atrial pacemakers, the model structure employed by the TAG is derived from that used in TA88 to assess the cost-effectiveness of these interventions in people with sick sinus syndrome (SSS) and no atrioventricular (AV) block (see Figure 9 in the assessment report). The cycle length of the model is 1 month, as, according to clinical experts, 1 month is sufficient for patients to feel the benefit of pacemaker implantation.

Patients enter the model requiring a pacemaker and are assigned to receive either a dual-chamber pacemaker ("Implant dual-chamber

pacemaker"; n=1,000) or a single-chamber atrial pacemaker ("Implant single-chamber atrial pacemaker"; n=1,000). After implantation of the respective pacing devices, patients transition into the "With pacemaker" health states; that is, the "With dual-chamber pacemaker" and "With single-chamber atrial pacemaker" health states.

The risk of reoperation is only possible for patients initially implanted with a single-chamber device. Based on a subgroup analysis of reoperation data from DANPACE, all patients requiring reoperation are assumed to receive a dual-chamber device. Analysis of reasons for reoperation in DANPACE indicated that a statistically significantly larger proportion of people who initially received a single-chamber pacemaker required reoperation to change pacing mode compared with those who received a dual chamber pacemaker (see Table 37 in the assessment report): all other reasons for reoperation were found to be not statistically significant.

For people implanted with single-chamber atrial devices, the need to change pacing mode is predominantly a result of the development of atrioventricular (AV) block requiring upgrade to a dual-chamber device. Therefore, to capture this statistically significant difference in the need for reoperation between the two pacemaker types, the cost and quality of life (QoL) of patients requiring a reoperation was based on the difference in event rates between the two arms and was applied in the model solely to patients receiving a single-chamber atrial device. This simplification in the model was tested in a structural sensitivity analysis (see Section 5.2.12 in the assessment report).

Furthermore, to maintain the focus of the model on the statistically significant difference between the device arms attributed solely to reoperation to change pacing mode, only one instance of reoperation was permitted within the model time horizon.

Patients residing in the "With pacemaker" health states are at risk of developing the sequelae of atrial fibrillation (AF), stroke or heart failure (HF), and patients who develop HF or stroke remain at risk of reoperation; however, in the event of reoperation, patients do not transition from the "HF" or "Stroke" health states, but instead simply incur the cost of reoperation. Patients who develop AF are at risk of the further sequelae of HF or stroke. However, once patients develop AF they are at no further risk of reoperation, as, after consultation with clinical experts, it has been assumed that, on development of AF, pacing will either cease or patients will be given a ventricular pacing device.

See Section 5 in the assessment report for more information on cost-effectiveness analysis.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document

called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

Summary of Appraisal Committee's Key Conclusions

Availability and Nature of Evidence

No submissions or economic models were provided by the manufacturers. The Assessment Group constructed a Markov cohort model from the perspective of the National Health Service (NHS) and Personal Social Services. The model had a cycle length of 1 month. Costs and health effects were discounted at an annual rate of 3.5%.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

With costing devices, rather than list prices, the Assessment Group had used a weighted average of Healthcare Resource Group (HRG) codes because they included the costs of the whole procedure. The Committee noted that a weighted average could disguise the true cost of more expensive devices. However, it heard from the clinical experts that there was no incentive for clinicians to use unnecessarily expensive dual-chamber devices. The Committee also noted the Assessment Group had conducted a threshold analysis on the impact of device costs on the incremental cost-effectiveness ratio (ICER). This indicated that the price difference between dual- and single-chamber atrial pacemakers had to be increased substantially, and to a level unlikely to be seen in clinical practice, before dual-chamber pacemakers would not be cost effective at a maximum acceptable ICER of £20,000 per quality adjusted life year (QALY) gained.

Incorporation of Health-related Quality-of-Life Benefits and Utility Values. Have Any Potential Significant and Substantial Health-related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

The Committee noted that there were no statistically significant differences shown for quality of life. However dual-chamber pacemakers had been clearly demonstrated to statistically significantly reduce the need for re-operation, which could be unpleasant and severe. The Committee concluded this was a significant benefit for patients.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost Effective?

Not applicable

What Are the Key Drivers of Cost-effectiveness?

The Committee agreed that there were high levels of uncertainty in the Assessment Group base-case ICERs, as a list price for the devices was not available to use in the model. However the threshold analysis had demonstrated that the price difference between dual- and single-chamber atrial pacemakers had to be increased substantially, and to a level unlikely to be seen in clinical practice, before dual-chamber pacemakers would not be cost effective at a maximum acceptable ICER of £20,000 per QALY. In sensitivity and scenario analyses, most ICERs were under £20,000 per QALY gained.

Most Likely Cost-effectiveness Estimate (Given as an ICER)

The Committee agreed that the base-case ICER of approximately £6000 per QALY gained was likely to be higher in clinical practice because there is no difference in the effectiveness of dual-chamber pacing for outcomes including heart failure. Dual-chamber pacemakers also have higher acquisition costs; however this cost is likely to be partially offset by the reduced need for re-operation. The Committee was further reassured by

the threshold analysis that the price difference between dual- and single-chamber atrial pacemakers had to be increased substantially, and to a level unlikely to be seen in clinical practice, before dual-chamber pacemakers would not be cost effective at a maximum acceptable ICER of £20,000 per QALY gained. The Committee concluded that the most plausible ICER was likely to be under £20,000 per QALY gained.

How Has the New Cost-effectiveness Evidence That Has Emerged since the Original Appraisal (TA88) Influenced the Current Recommendations?

Several new trials have been published since the publication of TA88. In particular, DANPACE was a large high-quality trial, providing the best evidence base for this appraisal. This indicated that dual-chamber pacemakers were associated with a statistically significant reduction in the need for re-operation compared with single-chamber atrial pacemakers.

### Method of Guideline Validation

External Peer Review

Internal Peer Review

### Description of Method of Guideline Validation

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the Technology Assessment Group (TAG). The main clinical effectiveness evidence came from 6 randomised controlled trials. For cost-effectiveness, the Appraisal Committee considered an economic model submitted by the TAG.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

The Committee concluded that dual-chamber pacemakers had been clearly demonstrated to statistically significantly reduce the need for re-operation compared with single-chamber atrial pacemakers.

### Potential Harms

- Dual-chamber pacemakers may be associated with a number of adverse reactions. The need for an additional lead in dual- compared with single-chamber pacemakers might lead to an associated increased risk of complications, such as lead displacement, puncture of the lung when placing the leads and infection of the pacemaker pocket or the leads. Complications arising after pacemaker implantation may include

dysfunction of the pacemaker or of the leads (that is, failure to pace or sense appropriately), infection or erosion of the pacemaker site or its leads and the development of pacemaker syndrome, stroke, heart failure or atrial fibrillation. Re-operation may be needed as a result of a complication or end-of-battery life. The complication rate associated with a re-operation to remove or replace leads is higher than that associated with initial implantation. Battery replacement has a very low complication rate when the leads do not need to be removed or replaced.

- The Assessment Group noted that although the dual-chamber pacemakers in DANPACE (2011) were programmed in a way intended to reduce unnecessary ventricular pacing, ventricular pacing was still 65% (with a range of ±33%), which may have offset some of the benefit of implanting a dual-chamber pacemaker. The clinical experts were in agreement that dual-chamber pacemakers implanted for the treatment of symptomatic bradycardia as a result of sick sinus syndrome without atrioventricular block should use algorithms that minimise unnecessary ventricular pacing. However, they noted that the dual-chamber pacemakers that have come to market since the publication of DANPACE have been developed to reduce the risk of unnecessary ventricular pacing, and a typical dual-chamber pacemaker used in clinical practice in England would now be expected to unnecessarily pace only around 10% of ventricular beats.

# Qualifying Statements

## Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

# Implementation of the Guideline

## Description of Implementation Strategy

- Section 7(6) of the National Institute for Health and Care Excellence (NICE) (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, National Health Services (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.
- When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraph above. This means that, if a patient has symptomatic bradycardia due to sick sinus syndrome without atrioventricular block and the doctor responsible for their care thinks that a dual-chamber pacemaker is the right treatment, it should be available for use, in line with NICE's recommendations.
- NICE has developed a costing statement explaining the resource impact of this guidance to help organisations put this guidance into practice.

## Implementation Tools

Foreign Language Translations

Mobile Device Resources

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

Living with Illness

## IOM Domain

Effectiveness

Patient-centeredness

# Identifying Information and Availability

## Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block (part review of technology appraisal guidance 88). London (UK): National Institute for Health and Care Excellence (NICE); 2014 Nov. 55 p. (Technology appraisal guidance; no. 324).

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2005 Feb (revised 2014 Nov)

## Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

## Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

## Guideline Committee

Appraisal Committee

## Composition of Group That Authored the Guideline

*Appraisal Committee Members*: Professor Andrew Stevens (*Chair of Appraisal Committee C*), Professor of Public Health, University of Birmingham; Professor Eugene Milne (*Vice Chair of Appraisal Committee C*), Director of Public Health, City of Newcastle upon Tyne; Professor Kathryn Abel, Director of Centre for Women's Mental Health, University of Manchester; Dr David Black, Medical Director, NHS South Yorkshire and Bassetlaw; David Chandler, Lay Member; Gail Coster, Advanced Practice Sonographer, Mid Yorkshire Hospitals NHS Trust; Professor Peter Crome, Honorary Professor, Department of Primary Care and Population Health, University College London; Professor Rachel A Elliott, Lord Trent Professor of Medicines and Health, University of Nottingham; Dr Greg Fell, Consultant in Public Health, Bradford Metropolitan Borough Council; Dr Alan Haycox, Reader in Health Economics, University of Liverpool Management School; Emily Lam, Lay Member; Dr Nigel Langford, Consultant in Clinical Pharmacology and Therapeutics and Acute Physician, Leicester Royal Infirmary; Dr Allyson Lipp, Principal Lecturer, University of South Wales; Dr Claire McKenna, Research Fellow in Health Economics, University of York; Professor Gary McVeigh, Professor of Cardiovascular Medicine, Queens University Belfast and Consultant Physician, Belfast City Hospital; Dr Andrea Manca, Health Economist and Senior Research Fellow, University of York; Professor Stephen O'Brien, Professor of Haematology, Newcastle University; Dr Anna O'Neill, Deputy Head of Nursing & Healthcare School/Senior Clinical University Teacher, University of Glasgow; Alan Rigby, Academic Reader, University of Hull; Professor Peter Selby, Consultant Physician, Central Manchester University Hospitals NHS Foundation Trust; Professor Matt Stevenson, Technical Director, School of Health and Related Research, University of Sheffield; Dr Paul Tappenden, Reader in Health Economic Modelling, School of Health and Related Research, University of Sheffield; Professor Robert Walton, Clinical Professor of Primary Medical Care, Barts and The London School of Medicine & Dentistry; Dr Judith Wardle, Lay Member; Dr Paul Miller, Director, Payer Evidence, Astrazeneca UK Ltd

## Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: National Institute for Clinical Excellence (NICE). Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block. London (UK): National Institute for Clinical Excellence (NICE); 2005 Feb. 36 p. (Technology appraisal; no. 88).

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

## Availability of Companion Documents

The following are available:

- Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block (part review of technology appraisal guidance 88). Costing statement. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Nov. 3 p. (Technology appraisal guidance; no. 324). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Edwards SJ, Karner C, Trevor N, Wakefield V, Salih F. Dual-chamber pacemakers for treating symptomatic bradycardia due to sick sinus syndrome without atrioventricular block: a multiple technology appraisal. Assessment report. London (UK): BMJ Technology Assessment Group (BMJ-TAG); 2014 Jul 2. 292 p. Electronic copies: Available from the NICE Web site .

## Patient Resources

The following is available:

- Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block (part review of technology appraisal guidance 88). Information for the public. London (UK): National Institute for Health and Care Excellence (NICE); 2014 Nov. 3 p. (Technology appraisal guidance; no. 324). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available for download as a Kindle or EPUB ebook from the NICE Web site . Also available in Welsh from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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